*Contains Nonbinding Recommendations*

**Draft Guidance on Amoxicillin**

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

**Active ingredient:** Amoxicillin

**Form/Route:** Capsules/Oral

**Recommended studies:** 2 studies

1. Type of study: Fasting
   Design: single-dose, two-treatment, two-period, crossover in vivo
   Strength: 500 mg
   Subjects: Healthy males and non-pregnant females, general population.
   Additional Comments:

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2. Type of study: Fed
   Design: single-dose, two-treatment, two-period, crossover in vivo
   Strength: 500 mg
   Subjects: Healthy males and non-pregnant females, general population.
   Additional Comments:

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**Analytes to measure (in appropriate biological fluid):** Amoxicillin in plasma

**Bioequivalence based on (90% CI)**: Amoxicillin

**Waiver request of in-vivo testing:** 250 mg based on (i) acceptable in vivo bioequivalence studies on the 500 mg strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths.

**Dissolution test method and sampling times:**

Please conduct comparative dissolution testing on 12 dosage units of all strengths of the test and reference products using the methods specified in the current USP. Specifications will be determined upon review of the application.